Digital health and patient safety: Technology is not a magic wand

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Digital health and patient safety: Technology is not a magic wand

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Abstract

The use of novel health information technology provides avenues for potentially significant patient benefit. However, it is also timely to take a step back and to consider whether the use of these technologies is safe – or more precisely what the current evidence for their safety is, and what kinds of evidence we should be looking for in order to create a convincing argument for patient safety. This special issue on patient safety includes eight papers that demonstrate an increasing focus on qualitative approaches and a growing recognition that the sociotechnical lens of examining health information technology–associated change is important. We encourage a balanced approach to technology adoption that embraces innovation, but nonetheless insists upon suitable concerns for safety and evaluation of outcomes.

Keywords

artificial intelligence, human factors, IT healthcare evaluation, machine learning, patient safety

Introduction

Populations are ageing, with an increasing number of people living with long-term conditions. Simultaneously, healthcare is becoming increasingly complex with an ever-growing range of diagnosis and treatment options. Health information technology (HIT) can make care safer and more efficient, but it can also have unanticipated consequences and contribute to adverse events.[1–4]

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However, the pace with which novel technologies are entering health services and the scale of change that they bring with them are unprecedented. Therefore, there is a need to monitor developments carefully and mitigate risks where they arise. In particular, there is currently a strong international interest in the use of artificial intelligence (AI) to revolutionise the way care is delivered.[5] While only at the beginning of this development, the achievements with AI in healthcare have been remarkable, albeit mainly in specific areas such as identifying pathologies through images, and mainly when augmenting as opposed to replacing human activities.[6–8] In the future, AI systems might move beyond offering advice to clinicians and patients and take decisions independently. For example, autonomous infusion pumps might determine appropriate infusion rates or decide when to take a patient off medication without input from a doctor.[9] However, empirical evidence shows that although AI systems tend to perform well in designated tasks, integration into complex sociotechnical environments (including a range of human stakeholders with different interests and other technologies) is still challenging. This may be partly due to HIT currently being in a transitionary period where a mix of old and new practices and artefacts exist, with the old being gradually replaced by the new.

These are exciting developments, and the use of novel HIT provides avenues for potentially significant patient benefit. However, it is also timely to take a step back and to consider whether the use of these technologies is safe – or more precisely what the current evidence for their safety is, and what kinds of evidence we should be looking for in order to create a convincing argument for patient safety. This is further complicated by the nature of innovation, where there is often a tension between the need for evidence of effectiveness and the drive for fast-paced technological innovation.

Evaluation of technology and evaluation of services

Independent evaluation studies are undertaken still too infrequently. This independent scrutiny is critical, because experience has shown that where there is an independent evaluation, the headline figures suggested by studies by technology developers are often over-optimistic.[10] For example, an independent evaluation of 23 patient-facing symptom checkers found that the correct diagnosis was listed as the most probable one in only around one-third of the test cases.[11] Health informatics evaluations are seldom replicated[12] and often do not follow good practice in reliable measurement of outcomes.[13] Formative evaluations that can help to shape developments and mitigate risks associated with new applications are also done far too infrequently, and where they exist, they are often misaligned with commercial and political timescales. As a result, formative insights may fail to inform concurrent decision-making and thereby not allow to mitigate risks.

Reliability and accuracy of HIT are important, but what all stakeholders need to know is whether the use of technology to deliver care is safe. Reliability figures by themselves do not allow prediction of what will happen when technology is integrated into social and clinical systems, when, for example, a clinician is confronted with a confusing user interface, an opportunity to interact with technology that was not foreseen or a digital workflow that impacts upon established team relationships and task management.

Understanding and evaluating these issues requires a sociotechnical rather than a technology-driven approach.[14] It has been argued that the expected rigour of undertaking evaluation should not be lowered for HIT, and for digital products, more generally, when compared with traditional interventions, and new types of clinical trial designs have been proposed.[15] HIT is difficult to evaluate because it is often associated with transformation and wider organisational and social changes, so it is harder to establish a baseline for comparison and to demonstrate a direct impact.[16] One might add to that the need to complement clinical trials with rigorous mixed-methods

approaches and realist evaluation studies[17] that are well suited to provide evidence about whether, how and under what circumstances new technologies can contribute to the quality and safety of care delivered to patients.[18] There is an increasing awareness of the value of such studies among health services researchers and policy makers, but there is still much dialogue and education required to build a shared awareness between technology implementers and evaluators. This could, for example, be achieved through teaching formative sociotechnical evaluation methods to HIT implementers, by making academic tools more user-friendly and by requiring evaluation plans to be explicit and funded in project business cases. There are obvious common interests between HIT implementers and healthcare quality improvement teams, which perhaps have not yet been widely integrated in organisational programmes.

The contribution of the papers in this special issue

As the papers in this special issue illustrate, there is an increasing focus on qualitative approaches and a growing recognition that the sociotechnical lens of examining HIT-associated change is important.

Sittig et al.[19] provide a review of nine key challenges for the safety of HIT that need to be addressed in the short to medium term. They structure these challenges around design and development, implementation and use, and monitoring, evaluation and optimisation. They usefully describe this structure as safe technology, safe use of technology and use of technology to improve safety. This approach demonstrates how the sociotechnical systems perspective moves beyond simplistic technology-focused evaluations of HIT.

The paper by Dean Franklin and Puaar[20] describes the result of a stepped wedge study of the impact of introducing electronic prescribing on prescribing errors in one hospital with 20 wards. The study nicely demonstrates the importance of having a robust study design that allows a nuanced analysis of the effect of technology on process and outcome measures. This study has a quantitative design, but the authors argue that further qualitative research is required in order to fully understand how and why HIT changes practice and outcomes.

Such a complementary approach is demonstrated in the paper by Furniss et al.[21] Their paper describes findings from a qualitative study of a closed-loop smart pump system in one intensive care unit. The paper illustrates how the technology can both contribute to and compromise patient safety. This qualitative, sociotechnical analysis of work-as-done supports our understanding of the impact of the introduction of technology on patient safety.

Ash et al.[22] provide further qualitative insights into how HIT is used and by whom. Their paper describes the findings of a qualitative study that aimed to identify what kinds of activities are performed within healthcare provider organisations to ensure electronic health record (EHR) safety. Based on interviews with 91 participants from six organisations, they describe the different types of activities that appear to be important for ensuring EHR safety from an organisational perspective. A key insight that comes from the paper is the suggestion that we should understand EHR safety not simply as a technical issue but analyse, measure and improve it at different levels.

The contributions by Habli et al.[23] and by Igene and Johnson[24] demonstrate how sociotechnical analysis of HIT can be undertaken proactively during design and reactively in case an adverse event or incident has taken place. Habli et al. describe the development and piloting of a software-supported approach to the proactive risk identification and risk analysis of Health IT products. This SMART (Safety Modelling, Assurance and Reporting Toolset) tool was applied to the study of an electronic prescribing and allergy management system. This proactive tool is intended to facilitate the application of National Health Service (NHS) Digital safety standards by incorporating the logic of the standards into the tool. Igene and Johnson describe the application of four different

analysis methods to identify factors that contribute to adverse events. These approaches have been in used in other industries, and their value in healthcare is assessed in this paper.

AI is the topic of the final two papers in this special issue. Evans et al.[25] report the automatic analysis of 31,000 patient safety incident reports from primary care settings. They use three different machine learning approaches for comparison. The aim was to automatically classify incident type and severity. Such an AI-driven approach could help with processing the large amounts of safety data that is generated by healthcare organisations, and lessons could be identified that apply across providers. The paper by Vehí et al.[26] demonstrates the potential positive effect on patient safety of using AI and machine learning approaches. They describe the application of machine learning to the prediction of hypoglycaemic events in type 1 diabetic patients. While the proposed system is a pilot study, the paper illustrates what personalised care supported by AI could look like. There are challenges around the validation of such an approach, and testing it in real life, because as previous papers have shown, the introduction of technology might have unanticipated effects or might need to consider factors other than those included in the original study.

Integration of patient safety into digital health innovations

The papers included in this issue exemplify the range of existing HIT applications and the challenges associated with evaluating their impact on safety, either directly or indirectly through changing the way organisations, teams and individuals operate. We can see that there are now a range of established applications that have paved the way for the development of frameworks that can guide assessments of the range of dimensions that are likely to impact safety. These now need to be applied prospectively to newer applications that currently operate in settings with a limited number of social actors. There is political and commercial pressure to make a 'leap of faith' that technology will provide sufficient benefits to outweigh the risks of untried changes in clinical work. There are already cases where it may legitimately be considered unsafe not to adopt technical solutions, but there are also many situations where to do so simply because of technology push would be unwise and unethical. We encourage a balanced approach that embraces innovation, but nonetheless insists upon suitable concerns for safety and evaluation of outcomes.

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